Reference: 24680  
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Adj. Professor John Skerritt

Deputy Secretary

Health Projects Regulation Group

Department of Health

Dear Professor Skerritt

# Regulation Impact Statement – Second-Pass Final Assessment – Regulatory Scheme for Personal Medical Devices

Thank you for forwarding a Regulation Impact Statement (RIS) to the Office of Best Practice Regulation (OBPR) for second-pass final assessment on 4 December 2019, examining proposed changes to the regulation of personal medical devices.

I acknowledge the complexity of the issues involved and the challenges in addressing a problem for which there is little evidence base of adverse outcomes or likely future behavioural responses to reforms. While the RIS would have benefitted from further examination of the costs of inaction, it clearly explains the rationale for the proposed reforms and the first order impacts on the sector. It also reflects robust stakeholder consultation and reasonable efforts made to investigate potential flow-on impacts on the market.

Given this, our assessment is that the level of analysis is commensurate with the problem and the RIS is consistent with best practice. The RIS is compliant with Australian Government RIS requirements and may now be provided to the decision maker to inform a final decision.

We would appreciate you advising us when a final decision on this proposal, or any measures it informs, has been announced and forwarding us a copy of the RIS in a form meeting the Government’s accessibility requirements. The OBPR’s reference number for this matter is 24680. If you have any further queries please do not hesitate to contact me.

Yours sincerely

Jason Lange

Executive Director

6 December 2019